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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,739	06/08/2001	John Russell Robertson	02332-0020 49409-264826	9829
23370 7590 05/26/2004 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
DATE MAILED: 05/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/857,739	<b>Applicant(s)</b> ROBERTSON ET AL.	
	<b>Examiner</b> MISOOK YU, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> .            |

### **DETAILED ACTION**

Applicant's submission of new Fig. 4, ~~abstract~~<sup>m7</sup>, and response filed on 3/8/2004 are acknowledged. Claims 1-4 are pending and under consideration. Claims 1-4 are examined as they are drawn to as to the extent they are drawn to the elected species of MUC1 as stated in the previous Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### ***Specification, Withdrawn***

The objection of record is withdrawn in view of the submission of new Fig. 4.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 10 December 1998. It is noted, however, that applicant has not filed a certified copy of the GB9827228.9 application as required by 35 U.S.C. 119(b). Applicant has not submitted the required document for claiming foreign priority. It is noted that applicant will supply the document.

### ***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because of applicant's persuasive argument.

***Claim Rejections - 35 USC § 103***

Claims 1-4 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over either von Mensdorff-Pouilly et al, Eur J Cancer. 1996 Jul;32A(8):1325-31, or Gourevitch et al, Br J Cancer. 1995 Oct;72(4):934-8 in view of Petrarca et al, Eur J Cancer. 1996 Nov;32A(12):2155-63.

Based on applicant's election of MUC1 as species, claims 1-4 are interpreted as drawn to method using MUC-1 autoantibody for detecting circulating MUC-1 antigen in sera from benign to advanced cancer patients with or without treatment.

Applicant argues that Mensdorff-Pouilly et al or Gourevitch et al, fail to detection of a cancer-associated marker protein, particularly MUC-1 per se, but the instant claims 1-4 do not say anything about detection of a cancer-associated marker protein, particularly MUC-1 per se. Claim 1 (b) says that the claimed invention is "detecting the presence of **any complexes**". Instant claim 1 as currently construed includes detection of serum MUC-1 complexed with something else. Therefore, applicant is arguing a limitation not present in the claims.

Applicant further argues that Mensdorff-Pouilly et al or Gourevitch et al do not teach the claimed invention but teach detection of a MUC-1 autoantibody complex with a murine monoclonal antibody. Based on teachings of the art of record, one would not be motivated to use the MUC-1 autoantibody for detection of circulating MUC-1 autoantibody, and one would not expect to succeed in detection of the serum cancer-associated MUC-1 antigen with the autoantibodies. These arguments have been fully considered but found unpersuasive for following reasons.

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Either von Mensdorff-Pouilly et al., or Gourevitch et al., teach presence of circulating MUC-1 in sera of patients with various cancer status, from benign to advanced cancer. Note page 936 and Fig. 2 of Gourevitch et al and Tables 1-6 of von Mensdorff-Pouilly. The presence of circulating MUC-1 in sera of patients from benign to advanced cancer in the two primary references was detected with monoclonal antibody, not MUC-1 autoantibody.

Either von Mensdorff-Pouilly et al., or Gourevitch et al., do not teach MUC-1 autoantibody. However, Petrarca et al., teach how to prepare MUC-1 autoantibody that meets the definition of "autoantibody" according to the specification at page 3 lines 25-33 "an naturally occurring antibody in that it recognizes the said self-originated antigen but which is produced outside the body, for example, by an immortalized cell". Petrarca et al at page 2161, last two paragraphs also teach that the MUC-1 autoantibody is "capable of successfully binding to ...circulating antigen", indicating that the MUC-1 autoantibody is a functional equivalent of the monoclonal antibody capable of presence of circulating MUC-1 in sera of patients from benign to advanced cancer.

Thus, the art of record as a whole teach every element of the claimed invention. Since the art of record teaches that autoantibody capable of detecting circulating MUC-1 cancer marker many different cancer patients, one of ordinary skill would be motivate to screen serum MUC-1 fragment for cancer screening with the autoantibodies taught by Petrarca et al., since autoantibody to MUC-1 is the functional equivalent of the antibody used in either von Mensdorff-Pouilly et al., or Gourevitch et al., for the detection of MUC-1 complex in serum from many cancer patients. Since all the

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necessary technical steps and reagents for the in vitro assay are taught in the three references, the claimed in vitro assay could be accomplished with reasonable expectation of success.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina C Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
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LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER